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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/934,207	08/21/2001	Imre Kovesdi	213187	8411

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EXAMINER

PRIEBE, SCOTT DAVID

ART UNIT

PAPER NUMBER

1633

DATE MAILED: 07/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/934,207	Applicant(s) KOVESDI ET AL.	
	Examiner Scott D. Priebe, Ph.D.	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The Art Unit designation of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Primary Examiner Scott D. Priebe, Ph.D., Group Art Unit 1633.

Interference No. 105046 has been terminated by a decision adverse to applicant. *Ex parte* prosecution is resumed.

Interference

Claims 36-55 are rejected under the principles of *res judicata* and collateral estoppel as being obvious over or not patentably distinct from count 1 in Interference No. 105046 involving Applicant's patent US 5,994,106 and Imler et al. application 09/725,720 (US 2001/0049136), which count was lost to Applicant (see *In re Deckler*, 24 USPQ2d 1448 (Fed. Cir. 1992));

or alternatively, under the principle of estoppel under then 37 CFR 1.658(c) (now 37 CFR 41.127(a)(1)) for failing to move under then 37 CFR 1.633 (now 37 CFR 41.121) to add the instant application or its claimed subject matter to the '046 interference (see MPEP 2363.03).

Claims 1-20 of the '106 patent were deemed to be obvious over or embraced by count 1 of the '046 interference. Instant claims 36-55 differ from claims 1-20 of the '106 patent only by inclusion of a "pharmaceutically acceptable carrier" in the instant claims. However, the addition of this limitation does not define an invention that is separately patentable from claims 1-20 of the '106 patent. A stock of an adenoviral vector, such as claimed in the '106 patent, would have routinely been suspended after its manufacture and purification in a pharmaceutically carrier,

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such as a sterile buffer, that was compatible for using the adenovirus in the stock, usually after dilution into a carrier, for transfecting mammalian cells either in cell culture or in a mammal. In other words, the presence of a pharmaceutically acceptable carrier in the stocks of the '106 patent would have been implicit in most embodiments to one of skill in the adenoviral vector art.

Even if the inclusion of "pharmaceutical carrier" in the stock of the '106 patent would define a separately patentable invention, Applicant is estopped from pursuing this subject matter for having failed to move, under then 37 CFR 1.633, to add the instantly claimed subject matter to the '046 interference. Imler's application 09/725,720, the winning party of the '046 interference, also discloses preparing compositions comprising the adenovirus vectors in a pharmaceutically acceptable carrier (see page 22, line 2 to page 23, line 4 of the '720 specification as filed, or its corresponding published application US 2001/0049136 at ¶¶ 0109-0115).

Claim Objections

The copy of the claims filed 11/3/03 is objected to because the amendment does not comply with 37 CFR 1.121(c)(1). The amendment filed 11/3/03 does not include a complete listing of all claims presented, specifically it does not list claims 1-35, which have been cancelled. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

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Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 36-55 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 36-38, 49, 51-54, 68-70, 72-76, 90, 91, 93-100, and 102-114 of copending Application No. 09/261,922. Although the conflicting claims are not identical, they are not patentably distinct from each other because the system and methods of the '922 are specifically designed to produce compositions (stocks) of the same adenoviral vectors of the instant claims, and cannot be practiced without making the compositions. The specification of the '922 application discloses that such stocks produced with the claimed system and by the claimed methods are intended for *ex vivo* or *in vivo* use requiring a pharmaceutically acceptable composition. The intended use of the instant compositions as a pharmaceutical does not distinguish the instant compositions from pharmaceutically acceptable compositions of the patent.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

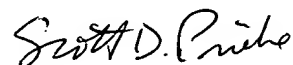
Applicant has previously indicated that this provisional rejection will be addressed when it is no longer provisional.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe, Ph.D. whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Scott D. Priebe, Ph.D.
Primary Examiner
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